

2004-2005 Influenza Season Vaccine Shortage

On October 5, 2004, the British equivalent of the Food and Drug Administration (FDA) suspended the license of the Liverpool influenza vaccine manufacturing plant owned by Chiron Corporation, resulting in the loss of 48 million doses of influenza vaccine bound for the U.S. market. Instead of the expected 100 million doses, ultimately, there will be at least 61 million doses of influenza vaccine for Americans, including 58 million doses of trivalent inactivated vaccine from

Aventis Pasteur and 3 million doses of FluMist, MedImmune's live-attenuated nasal-spray vaccine. At press, a decision was pending from the FDA on the importation of up to 5 million doses of influenza vaccine from overseas.

In response to the shortage, the Centers for Disease Control and Prevention (CDC) and the Advisory Committee on Immunization Practices (ACIP) issued emergency changes to the

groups recommended for influenza vaccination this season; these focused on protecting those at highest risk of morbidity and mortality. The new high priority groups (all of equal importance) include:

- Adults aged 50 years or older (as of January 3, 2005)
- Children aged 6 to 23 months
- Children up to 18 years on chronic aspirin ther-

(Continued on page 2)

Determinants of Influenza Immunization, 2003-2004: Shortages, Fallacies and Disparities

The influenza outbreak of 2003-2004 received substantial media attention including widespread reports of a severe season and vaccine shortages. To better understand determinants of vaccine receipt to help guide immunization policies, Tennessee EIP staff surveyed residents statewide regarding knowledge, beliefs and attitudes regarding influenza vaccination and their recent

experiences obtaining vaccine. Given the unexpected and severe shortage of influenza vaccine in 2004-2005, the results of this study are particularly important in better understanding how to improve vaccine acceptance in high-risk groups. The results of this survey were published in December.¹

From February through June, 2004 we adminis-

tered a structured telephone survey to Tennessee residents, using random-digit dialing methodology. Questionnaires were completed by 4033 persons. Of respondents, 52% had received influenza vaccination in the previous season; 63% received it at a private medical clinic, 14% at a workplace, 11% at a health department and 7% from a pharmacy. Three-fourths

(Continued on page 3)

Inside this issue:

2004-2005 Influenza Season Vaccine Shortage	1-2
Determinants of Influenza Immunization, 2003-2004: Shortages, Fallacies and Disparities	1,3
UPDATE: Methicillin-Resistant <i>Staphylococcus aureus</i>	4

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You can also visit us on the web at <http://tennessee.gov/health> by clicking on Programs, then clicking on Emerging Infections Program.



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¹ Jones TF, Ingram LA, Craig AS, Schaffner W. Determinants of influenza immunization, 2003-2004: shortages, fallacies and disparities. Clin Infect Dis 2004;39:1824-1828.

2004–2005 Influenza Season Vaccine Shortage (continued)

(Continued from page 1)

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- Anyone aged 2 to 64 years with chronic medical conditions requiring regular medical care, such as asthma, heart or lung disease, or diabetes
- Residents of long-term care facilities
- Household contacts and out-of-home caregivers of infants aged <6 months
- Women who will be pregnant during influenza season
- Health care workers who provide direct, hands-on patient care.

The CDC estimates that the number of Americans falling into these high priority groups is about 95 million. In

a survey described in the *Morbidity and Mortality Weekly Report (MMWR)*, 30.0–39.9% of high-risk Tennesseans had been vaccinated as of December 1–11, 2004 (**Figure**).¹ Those persons who are not in one of the aforementioned priority groups are asked to forgo vaccination with an inactivated vaccine this season, but may use FluMist where available.

In order to make vaccine available to those in the high priority groups, the CDC and Aventis Pasteur began redistributing the 24 million doses of influenza vaccine remaining in warehouses to high priority customers, such as the federal Vaccines for Children (VFC) program, the VA hospital system, health departments, hospitals, long-term care facilities, and pediatricians that ordered vaccine

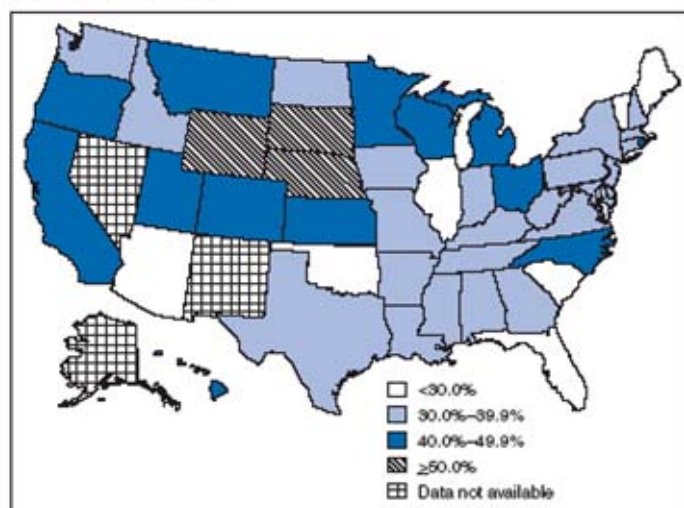
Tennessee Department of Health identified three priority groups for distribution of the state-controlled vaccine. The first priority group included residents and staff of long-term care facilities. The second was patient care staff of hospitals, while the remaining vaccine was to be made available to other high priority groups through county health department clinics.

In January, additional vaccine was distributed to private providers and health departments.

Interest in stretching the vaccine supply through intradermal injection has been reinforced by preliminary research published in the *New England Journal of Medicine* in November showing good response to this technique in healthy adults.^{2,3} Despite these initial promising findings, this strategy is not recommended at this time; additional studies will be needed to confirm these results, particularly in high-risk populations.

Vaccination is worthwhile for high priority patients at any point in the influenza season; however, public demand typically drops off sharply after Thanksgiving. The influenza season usually does not peak until the second or third week in January in Tennessee, and there had been just 12 culture-confirmed influenza A and two influenza B isolates reported as of January 8, 2005. Because vaccine will continue to arrive in the state through January, health care providers should continue to encourage high priority patients to be vaccinated whenever vaccine is available.

FIGURE. Percentage of adults in priority groups* reporting receiving influenza vaccination†, by state — Behavioral Risk Factor Surveillance System, United States, September 1–November 30, 2004



* Includes persons aged 18–64 years with asthma, other lung problems, heart problems, diabetes, kidney problems, weakened immune system, anemia, or pregnancy; persons aged ≥65 years; health-care workers with patient contact; and persons with children aged <6 months in the household. (Does not include residents of nursing homes and long-term-care facilities and out-of-home caregivers for children aged <6 months.)

† Interviews were conducted during December 1–11, 2004.

from Aventis. In order to reach private sector facilities that ordered from Chiron, the CDC apportioned the remaining 7.2 million doses of vaccine to state health officers to direct distribution within their states through January 2005.

Tennessee's apportionment was 98,000 adult doses; of these, 35,600 were available in January. In November, the

¹ CDC. Estimated influenza vaccination coverage among adults and children --- United States, September 1--November 30, 2004. *MMWR* 2004;53:1147-1153.

² Belshe RB, Newman FK, Cannon J, et al. Serum antibody responses after intradermal vaccination against influenza. *N Engl J Med* 2004;351:2286-94.

³ Kenney RT, Frech SA, Muenz LR, et al. Dose sparing with intradermal injection of influenza vaccine. *N Engl J Med* 2004;351:2295-301.

Determinants of Influenza Immunization, 2003-2004 (continued)

(Continued from page 1)

of respondents reported a risk factor for which CDC recommends immunization; of those, 41% went unvaccinated, including 783 (26%) who had seen a medical provider for other reasons during the influenza season. Over 40% of persons \geq age 50, over half of healthcare workers, and 70% of pregnant women were not immunized. Blacks, rural residents and lower-income respondents were significantly less likely to be immunized than comparison groups (Table 1). Of those vaccinated, 6% reported difficulties obtaining vaccine (most commonly stated that vaccine was not readily available). One-fourth of unvaccinated persons had been offered immunization but declined; 35% thought it unnecessary and 33% believed it would make them ill (Table 2). Of those not immunized, 8% reported requesting it but not receiving it, most commonly because it was unavailable.

This study demonstrates how the capacity and expertise of the Emerging

Table 1. Proportion of respondents immunized against influenza, by various characteristics

Characteristic	Immunized number (%)	Unimmunized number (%)	aOR*	p-value
Male	592 (48)	636 (52)	0.91	0.3
Female	1483 (53)	1314 (47)		
No college education (adults only)	941 (52)	852 (48)	0.83	0.06
Any college education (adults only)	1052 (51)	996 (49)		
White	1821 (53)	1617 (47)	1.51	0.002
Non-white	249 (43)	326 (57)		
Rural residence	677 (49)	709 (51)	0.74	0.0017
Nonrural residence	1393 (53)	1232 (47)		
Risk factor for which immunization	1769 (59)	1247 (41)	1.88	<0.0001
No risk factors	308 (30)	704 (70)		
Age \geq 50 years	1401 (66)	706 (34)	2.42	<0.0001
Age < 50 years	676 (35)	1245 (65)		

*adjusted odds ratios calculated from logistic regression analysis, adjusting for other variables.

Infections Program can be used to respond promptly to emerging public health threats and inform our response to new problems. Many barriers contribute to disparities in influenza vaccination, of which inadequate

supply is only one component. Myths regarding influenza vaccination persist tenaciously. A multifaceted approach to increasing immunization rates is critical.

Table 2. Primary reasons cited among respondents not immunized against influenza during the 2003-2004 season, by various characteristics

	Total unvaccinated	≥ 65 years old	≤ 64 years old	High risk medical condition	No high risk medical condition	CDC risk group ^Q	No CDC risk group	White	Non-white
Total unvaccinated (N)	1951	202	1749	426	1525	1247	704	1617	326
Reasons cited: N (%)									
Thought not necessary	641 (33)	55 (27)	596 (34)	116 (27)*	535 (35)	399 (32)	252 (36)	545 (34)	101 (31)
Believed would cause illness	409 (21)	59 (29)	350 (20)	122 (29)*	287 (19)	292 (23)*	117 (17)	321 (20)	87 (27)
Never thought about it	403 (21)	40 (20)	363 (21)	68 (16)*	335 (22)	227 (18)*	176 (25)	318 (20)	84 (26)
Side effects not worth it	195 (10)	23 (11)	172 (10)	37 (9)	158 (10)	126 (10)	69 (10)	152 (9)	42 (13)
Believed not effective	171 (9)	18 (9)	153 (9)	38 (9)	133 (9)	108 (9)	63 (9)	140 (9)	30 (9)
Cost barrier	50 (3)	4 (2)	46 (3)	17 (4)*	33 (2)	36 (3)	14 (2)	36 (2)	13 (4)
No time	98 (5)	7 (3)	91 (5)	19 (4)	79 (5)	61 (5)	37 (5)	81 (5)	17 (5)
Vaccine was not available	95 (5)	9 (4)	85 (5)	27 (6)	67 (4)	66 (5)	28 (4)	86 (5)	8 (2)
Never saw provider to ask	32 (2)	1 (0)	31 (2)	4 (1)	28 (2)	21 (2)	11 (2)	29 (2)	3 (1)

^Q- Persons noting any risk factor for which CDC specifically recommends vaccination.

*Significant difference compared to group without that characteristic ($p < 0.05$) on multivariate analysis.

UPDATE: Methicillin-Resistant *Staphylococcus aureus*

The following is an update regarding notifiable diseases and laboratory testing of *Staphylococcus aureus*.

The Tennessee Department of Health (TDH) Notifiable Diseases Report (<http://www2.state.tn.us/health/Downloads/ph-1600.pdf>) was recently modified to include invasive methicillin-resistant *Staphylococcus aureus* (MRSA) as a written reportable disease to the health department. This requires reporting of MRSA isolates from all normally sterile sites, i.e. blood, cerebral spinal fluid, or less commonly, joint, pleural, pericardial fluid, bone, organs and tissue. Not included, as normally sterile sites are the following specimens: urine, catheter tips, swabs (wound or any other site).

Because standard testing methodologies (disc diffusion and automated methods such as Vitek and Microscan) do not reliably detect vancomycin resistance in *S. aureus*, the Centers for Disease Control and Prevention (CDC) recommends adding a commercial van-

comycin 6mg/ml agar screening plate (the same agar plate that is used for vancomycin-resistant enterococcus (VRE) screening), <http://www.cdc.gov/ncidod/hip/Lab/FactSheet/vrsa.htm>.

The TDH is requesting that laboratories incorporate the addition of this vancomycin agar screening plate to their protocol. Laboratories may choose one of the following three options to implement this: (1) all MRSA isolates or (2) all *S. aureus* isolates or (3) all coagulase-positive Staphylococci. Algorithms to follow when vancomycin resistance is detected can be found at http://www.cdc.gov/ncidod/hip/Lab/FactSheet/visa_vrsa_algo.htm (Figure). Please be aware that all suspect or confirmed cases of vancomycin intermediate susceptibility *S. aureus* (VISA) and vancomycin-resistant *S. aureus* (VRSA) from ANY site (not just from sterile sites) are immediately (24/7) reportable to the TDH by telephone. Contact your local health department or the Tennessee

Department of Health at 615-741-7247.

A very useful resource for laboratorians has recently been developed by CDC to enhance understanding and improve proficiency in performing antimicrobial susceptibility testing (M.A.S.T.E.R.). This training can be accessed at <http://www.phppo.cdc.gov/dls/master/default.aspx>.

Cultures of certain organisms (including *Listeria monocytogenes*, *Haemophilus influenzae*, *Streptococcus pneumoniae*, *Neisseria meningitidis* (all from sterile sites only)) need to be submitted to the TDH State laboratory. A full list of these organisms can be found on page 46-47 of <http://www.state.tn.us/sos/rules/1200/1200-06/1200-06-03.pdf>.

If you have any questions or concerns regarding any of these aforementioned issues please feel free to contact Dr. Kainer at (615) 741-7247 or Dr. Kimberly at (615) 262-6300.

